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(Original Signature of Member)

109TH CONGRESS
1ST SESSION

H. R. _____

To direct the Secretary of Health and Human Services to require the incorporation of counterfeit-resistant technologies into the packaging of prescription drugs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. BURTON of Indiana introduced the following bill; which was referred to the Committee on _____

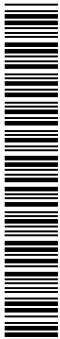
A BILL

To direct the Secretary of Health and Human Services to require the incorporation of counterfeit-resistant technologies into the packaging of prescription drugs, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Reducing Fraudulent
5 and Imitation Drugs Act of 2006”.



1 **SEC. 2. COUNTERFEIT-RESISTANT TECHNOLOGIES FOR**
2 **PRESCRIPTION DRUGS.**

3 (a) **REQUIRED TECHNOLOGIES.**—The Secretary of
4 Health and Human Services shall require that the pack-
5 aging of any prescription drug incorporate—

6 (1) radio frequency identification (RFID) tag-
7 ging technology, or similar trace and track tech-
8 nologies that have an equivalent function;

9 (2) tamper-indicating technologies; and

10 (3) blister security packaging when possible.

11 (b) **USE OF TECHNOLOGIES.**—

12 (1) **AUTHORIZED USES.**—The Secretary shall
13 require that technologies described in subsection
14 (a)(1) be used exclusively to authenticate the pedi-
15 gree of prescription drugs, including by—

16 (A) implementing inventory control;

17 (B) tracking and tracing prescription
18 drugs;

19 (C) verifying shipment or receipt of pre-
20 scription drugs;

21 (D) authenticating finished prescription
22 drugs; and

23 (E) electronically authenticating the pedi-
24 gree of prescription drugs.

25 (2) **PRIVACY PROTECTION.**—The Secretary shall
26 prohibit technologies required by subsection (a)(1)



1 from containing or transmitting any information
2 that may be used to identify a health care practi-
3 tioner or the prescription drug consumer.

4 (3) PROHIBITION AGAINST ADVERTISING.—The
5 Secretary shall prohibit technologies required by
6 subsection (a)(1) from containing or transmitting
7 any advertisement or information about prescription
8 drug indications or off-label prescription drug uses.

9 (c) RECOMMENDED TECHNOLOGIES.—The Secretary
10 shall encourage the manufacturers and distributors of pre-
11 scription drugs to incorporate into the packaging of such
12 drugs, in addition to the technologies required under sub-
13 section (a), overt optically variable counterfeit-resistant
14 technologies that—

15 (1) are visible to the naked eye, providing for
16 visual identification of prescription drug authenticity
17 without the need for readers, microscopes, lighting
18 devices, or scanners;

19 (2) are similar to technologies used by the Bu-
20 reau of Engraving and Printing to secure United
21 States currency;

22 (3) are manufactured and distributed in a high-
23 ly secure, tightly controlled environment; and



1 (4) incorporate additional layers of non-visible
2 covert security features up to and including forensic
3 capability.

4 (d) STANDARDS FOR PACKAGING.—

5 (1) MULTIPLE ELEMENTS.—For the purpose of
6 making it more difficult to counterfeit the packaging
7 of prescription drugs, the Secretary shall require
8 manufacturers of prescription drugs to incorporate
9 the technologies described in paragraphs (1), (2),
10 and (3) of subsection (a), and shall encourage manu-
11 facturers and distributors of prescription drugs to
12 incorporate the technologies described in subsection
13 (c), into multiple elements of the physical packaging
14 of the drugs, including—

15 (A) blister packs, shrink wrap, package la-
16 bels, package seals, bottles, and boxes; and

17 (B) at the item level.

18 (2) LABELING OF SHIPPING CONTAINER.—

19 Shipments of prescription drugs shall include a label
20 on the shipping container that incorporates the tech-
21 nologies described in subsection (a)(1), so that mem-
22 bers of the supply chain inspecting the packages will
23 be able to determine the authenticity of the ship-
24 ment. Chain of custody procedures shall apply to
25 such labels and shall include procedures applicable



1 to contractual agreements for the use and distribu-
2 tion of the labels, methods to audit the use of the
3 labels, and database access for the relevant govern-
4 mental agencies for audit or verification of the use
5 and distribution of the labels.

6 (e) PENALTY.—A prescription drug is deemed to be
7 misbranded for purposes of the Federal Food, Drug, and
8 Cosmetic Act (21 U.S.C. 301 et seq.) if the packaging or
9 labeling of the drug is in violation of a requirement or
10 prohibition applicable to the drug under subsection (a),
11 (b), or (d).

12 (f) TRANSITIONAL PROVISIONS; EFFECTIVE
13 DATES.—

14 (1) NATIONAL SPECIFIED LIST OF SUSCEP-
15 TIBLE PRESCRIPTION DRUGS.—

16 (A) INITIAL PUBLICATION.—Not later than
17 180 days after the date of the enactment of this
18 Act, the Secretary of Health and Human Serv-
19 ices shall publish in the Federal Register a list,
20 to be known as the National Specified List of
21 Susceptible Prescription Drugs, consisting of
22 not less than 30 of the prescription drugs that
23 are most frequently subject to counterfeiting in
24 the United States (as determined by the Sec-
25 retary).



1 (B) REVISION.—Not less than annually
2 through the end of calendar year 2009, the Sec-
3 retary shall review and, as appropriate, revise
4 the National Specified List of Susceptible Pre-
5 scription Drugs. The Secretary may not revise
6 the List to include fewer than 30 prescription
7 drugs.

8 (2) EFFECTIVE DATES.—The Secretary shall
9 implement the requirements and prohibitions of sub-
10 sections (a), (b), and (d)—

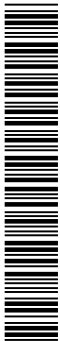
11 (A) with respect to prescription drugs on
12 the National Specified List of Susceptible Pre-
13 scription Drugs, beginning not later than the
14 earlier of—

15 (i) 1 year after the initial publication
16 of such List; or

17 (ii) December 31, 2007; and

18 (B) with respect to all prescription drugs,
19 beginning not later than December 31, 2010.

20 (3) AUTHORIZED USES DURING TRANSITIONAL
21 PERIOD.—In lieu of the requirements specified in
22 subsection (b)(1), for the period beginning on the ef-
23 fective date applicable under paragraph (2)(A) and
24 ending on the commencement of the effective date
25 applicable under paragraph (2)(B), the Secretary



1 shall require that technologies described in sub-
2 section (a)(1) be used exclusively to verify the au-
3 thenticity of prescription drugs.

4 (g) DEFINITIONS.—In this Act:

5 (1) The term “pedigree”—

6 (A) means the history of each prior sale,
7 purchase, or trade of the prescription drug in-
8 volved to a distributor or retailer of the drug
9 (including the date of the transaction and the
10 names and addresses of all parties to the trans-
11 action); and

12 (B) excludes information about the sale,
13 purchase, or trade of the drug to the drug con-
14 sumer.

15 (2) The term “prescription drug” means a drug
16 subject to section 503(b)(1) of the Federal Food,
17 Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)).

18 (3) The term “Secretary” means the Secretary
19 of Health and Human Services.

